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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,061	11/27/2001	Max Schaldach	7163-32	3174

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EXAMINER	
THALER, MICHAEL H	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/996,061	SCHALDACH ET AL.	
	Examiner	Art Unit	
	Michael Thaler	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 19-52* is/are pending in the application.

4a) Of the above claim(s) *7,9-13,19,20,35-40 and 42-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,14-17,21-34,51 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

This application contains claims 7, 9-13, 19, 20, 35-40 and 42-50 drawn to an invention and species nonelected with traverse in the response filed May 19, 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-3, 5, 21 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Atala (2003/0208279). Atala discloses a stent 10 for a vessel (note the term "blood vessels" in paragraphs [0002] and [0013]) comprising a tubular body (figure 1) for expansion from a first condition to a second condition (paragraph [0063]), the stent being configured such that a first part of the stent (e.g. the main part of the stent) is disposed inwardly relative to a second part of the stent (e.g. the bioactive compound attached to the surface of the stent as described in paragraph [0038]), wherein the tubular body includes at least a first wall portion comprising human or animal tissue (paragraphs [0013] and [0041]) of adequate elasticity (paragraph [0063]). As to claims 5 and 25, the Atala tissue is inherently capable of being hardened if and when a hardening agent is applied thereto.

Claims 4, 22-24 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atala (2003/0208279). Atala fails to disclose the tissue being genetically modified.

However, it is old and well known in this art to genetically modify tissue in order to obtain favorable characteristics for it. It would have been obvious to genetically modify the Atala tissue so that it too would have this advantage. The above well known in the art statement is taken to be admitted prior art because applicant failed to traverse the examiner's assertion (M.P.E.P. 2144.03).

Claims 1, 2, 5, 6, 25 and 30 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Turi (5,556,414). Turi discloses a stent 20 for a vessel (col. 1, lines 40-42) comprising a tubular body (figure 1) for expansion from a first condition to a second condition (col. 8, lines 1-5), the stent being configured such that a first part of the stent (e.g. 26) is disposed inwardly relative to a second part of the stent (e.g. 22), wherein the tubular body includes at least a first wall portion (the wall of the entire composite prosthesis 20) comprising human or animal tissue (26) of adequate elasticity. Alternatively, it would have been obvious that the tissue 26 of the Turi stent 20 has adequate elasticity since it expands with the cylindrical member 22. As to claims 6 and 30, Turi discloses hardening agent (the adhesive described in col. 5, lines 49-52).

Claims 4, 8, 22-24, 26-29, 32, 34 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turi (5,556,414). As to claims 4 and 22-24, Turi fails to disclose the tissue being genetically modified. However, it is old and well known in this art to genetically modify tissue in order to obtain favorable characteristics for it. It would have been obvious to genetically modify the Turi tissue so that it too would have this advantage. As to claims 8 and 41, Turi fails to disclose the hardening agent (adhesive) enclosed in microcapsules. However, it is old and well known in this art to enclose adhesive in microcapsules in order to obtain the advantage of easily deploying the adhesive on the surface. It would have been obvious to enclose the Turi adhesive in microcapsules so that it too would have this advantage. The above well known in the art statements are taken to be admitted prior art because applicant failed to traverse the examiner's assertions (M.P.E.P. 2144.03).

Claims 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turi (5,556,414) in view of Atala (2003/0208279). Turi fails to disclose the tissue being cartilage (noting that claims 31 indirectly depend from claim 3 and claim 33 indirectly depends from claim 21). However, Atala teaches that tissue on a stent should be cartilage (paragraph

[0041]) apparently in order to make the stent biocompatible (paragraph [0013]). It would have been obvious to make the Turi tissue cartilage so that it too would have this advantage.

Claims 14-17, 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turi (5,556,414) in view of Berg et al. (5,680,873). As to claim 14, Turi discloses a catheter comprising a distal end region (the distal portion of the balloon catheter 41) and a holding device for holding the stent (the balloon on the balloon catheter 41). Turi fails to disclose a sheathing device provided with an application device for applying a medium which is capable of flow to a surface of the stent. However, Berg et al. teach that a guide catheter 22 should be used with a balloon catheter in order to obtain the advantage of guiding the balloon catheter through the vasculature as well as delivering fluids to the body (col. 1, lines 13-21). It would have been obvious to include a guide catheter with the Turi balloon catheter so that it too would have this advantage. Note that the Berg et al. guide catheter 22 (the claimed sheathing device) has an application device (the feed passage of guide catheter 22 through which dye passes as described in col. 7, lines 17-20) which is provided at the sheathing device for applying a medium which is capable of flow to a surface of the stent. For example, after stent

implantation, the balloon catheter could be removed from the guide catheter and die could be delivered through the guide catheter to the stent. As to claim 15, Berg et al. disclose an application opening (at the extreme distal end of guide catheter 22). As to claim 16, the Berg et al. sheathing device 22 has an anti-adhesion coating 40 while Turi discloses a layer of adhesive in col. 5, lines 7-8 and 48-57. For this claim, the claimed stent may be considered to be only member 26 of Turi which includes a first part (the radially innermost portion of member 26) and a second part (the radially outermost portion of member 26). Note that the layer of adhesive on member 26 is on the surface of member 26 facing radially outwardly (i.e. toward the sheathing device as claimed).

Applicant's arguments filed Sep. 27, 2004 have been fully considered but they are not persuasive for the reasons set forth above. Further, as to claim 6, the adhesive described in col. 5, lines 49-52 of Turi is a hardening agent since it hardens as it cures or dries.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS

of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (571)272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

mht
12/8/04

MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731